

इंटरनेट

मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 12375-8 (1998): Implants for Surgery - Partial and Total Hip Joint Prostheses, Part 8: Endurance Performance of Stemmed Femoral Components with Application of torsion [MHD 2: Orthopaedic Instruments, Implants and Accessories]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

BLANK PAGE



भारतीय मानक

शल्य चिकित्सा के लिए अन्तर्रोपण — आंशिक और
संपूर्ण कूल्हे पर के जोड़

भाग 8 ऐंठन सहित अनुप्रयोग के डन्डीनुमा फेमोरल अवयवों की
सह्यता कार्यकारिता

Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL
HIP JOINT PROSTHESES

PART 8 ENDURANCE PERFORMANCE OF STEMMED FEMORAL COMPONENTS
WITH APPLICATION OF TORSION

ICS 11.040.40

© BIS 1998

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 7206-8:1995 'Implants for surgery — Partial and total hip joint prostheses — Part 8 : Endurance performance of stemmed femoral components with application of torsion' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to an International Standard for which Indian Standard also exists. The corresponding Indian Standard which is to be substituted in its place is given below along with its degree of equivalence for edition indicated :

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
7206-4 : 1989	IS 12375 (Part 4) : 1993 Implants for surgery — Partial and total hip joint prostheses : Part 4 Determination of endurance properties of stemmed femoral components with application of torsion	Identical

This standard has been issued in 9 parts. Other parts of this standard are:

- Part 1 Classification, designation of dimensions and requirements
- Part 2 Bearing surfaces made of metallic and plastic materials
- Part 3 Determination of endurance properties of stemmed femoral components without application of torsion
- Part 4 Determination of endurance properties of stemmed femoral components with application of torsion
- Part 5 Determination of resistance to static load of head and neck region of stemmed femoral components
- Part 6 Determination of endurance properties of head and neck region of stemmed femoral components
- Part 7 Endurance performance of stemmed femoral components without application of torsion
- Part 9 Determination of resistance to torque of head fixation of stemmed femoral components

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL HIP JOINT PROSTHESES

PART 8 ENDURANCE PERFORMANCE OF STEMMED FEMORAL COMPONENTS WITH APPLICATION OF TORSION

1 Scope

This part of ISO 7206 specifies the endurance performance of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joint replacement as determined under specified laboratory conditions by a method that includes the application of torsion.

This part of ISO 7206 does not apply to the following:

- a) prostheses for special clinical cases;
- b) prostheses for which the centreline of the stem is three-dimensionally curved and does not lie in any plane in which the axis of the neck lies.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 7206. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7206 are encouraged to investigate the

possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7206-4:1989, *Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties of stemmed femoral components with application of torsion.*

3 Test conditions

The femoral component shall be tested in its ready-for-use condition.

4 Endurance performance

When tested as described in ISO 7206-4, the femoral component shall not fracture during 5×10^6 cycles of application of a cyclic load of 2 kN with a minimum load of 300 N and a maximum load of 2,3 kN. Neither shall the tests have been terminated before completion of the loading regime (see ISO 7206-4:1989, subclause 7.8) for reasons other than loosening of the specimen in the embedding medium.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards : Monthly Additions'.

This Indian Standard has been developed from Doc : No. MHD 2 (2708).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 323 01 31, 323 94 02, 323 33 75

Telegrams: Manaksanstha
(Common to
all offices)

Regional Offices:

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg
NEW DELHI 110002

Telephone

{ 323 76 17
323 38 41

Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Maniktola
CALCUTTA 700054

{ 337 84 99, 337 85 61
337 86 26, 337 86 62

Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160022

{ 60 38 43
60 20 25

Southern : C. I. T. Campus, IV Cross Road, CHENNAI 600113

{ 235 02 16, 235 04 42
235 15 19, 235 23 15

Western : Manakalaya, E9 MIDC, Marol, Andheri (East)
MUMBAI 400093

{ 832 92 95, 832 78 58
832 78 91, 832 78 92

Branches : AHMADABAD. BANGALORE. BHOPAL. BHUBANESHWAR.
COIMBATORE. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR.
KANPUR. LUCKNOW. NAGPUR. PATNA. PUNE. THIRUVANANTHAPURAM.